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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,401	01/16/2002	Alfred Pollak	7126-2	8318

35743 7590 11/21/2003

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919 THIRD AVENUE  
NEW YORK, NY 10022

EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/913,401

Applicant(s)

POLLAK ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8/22/01; 4/21/03; 6/18/03; and 9/22/03.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 19-21, 24, 26-39, 41, and 42 is/are rejected.
- 7) ☒ Claim(s) 14-18, 22, 23, 25 and 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .                      6) ☐ Other: \_\_\_\_\_

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## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the following:
  - a. Paper No. 3, filed 8/22/03, wherein claims 1-3, 7, 10-19, 21, 22, 24, 26-29, 31, 32, 35-40, and 42 were amended.
  - b. Paper No. 8, filed 4/21/03, wherein the specification and claims 13 and 14 were amended.
  - c. Paper No. 12, filed 6/18/03, wherein the specification and claims 13 and 14 were amended.

**Note**: Claims 1-44 are pending.

## **APPLICANT'S INVENTION**

2. Applicant's invention is directed to a composition (and uses thereof) comprising a metal support surface and a conjugate wherein the conjugate is releasably bound to the support surface and comprises a ligand and a targeting moiety.

## **RESPONSE TO APPLICANT'S ELECTION**

3. Applicant's election of Group I, claims 1-42, in Paper No. 16, filed 9/22/03, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

## **WITHDRAWN CLAIMS**

4. Claims 43 and 44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

## **DOUBLE PATENTING REJECTION**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-13, 19-21, 24, 35-39, 41, and 42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, and 11-14 of U.S. Patent No. 5,789,555. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the instant invention, both the patent and the application claims are directed to a

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composition (and uses thereof) comprising a metal, a support surface, and a conjugate wherein the conjugate comprises a ligand and a targeting molecule. The claims differ in that the patent states that the support is solid and the application claims state that there is a metal support surface.

## 112 REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 2, 4, 7-13, 26-34, 38, 41, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4, 7, 8, 11- 13 27, and 38 are ambiguous because one cannot ascertain what 'small organic molecules' Applicant are claiming which are compatible with the instant invention. Furthermore, what does Applicant mean by the term 'small', a molecule having three atoms? Thus, Applicant is respectfully requested to clarify the claim in order that one may readily ascertain what is being claimed.

Claims 1, 2, 7-10, 27, 38, and 41 are ambiguous because of the term 'derivative'. For example, it is unclear which portion of the parent structure (i.e., 'cysteine amino acid residue derivative'; 'amino acid residue derivative'; 'polyamino polysulfide derivative'; 'tetradentate  $NxS4-x$  ligand derivatives'; and 'peptide, a peptide mimetic, a polypeptide or a polypeptide mimetic of about 3 to 50 amino acid residues or derivatives thereof) remains in the derivative. The removal of a hydrogen, carbon, oxygen, sulfur, etc.

would all result in the formation of a derivative. Please clarify the claim in order that one may readily determine what is being claimed.

Claims 26-34 are ambiguous because it is unclear what specific disease, disorder, or abnormal physical state Applicant is claiming to be compatible with the instant invention. Applicant is respectfully requested to clarify the claim in order that one may know what diseases, disorders, and/or abnormal physical state the claims are directed to.

#### **CLAIM OBJECTIONS**

9. Claims 14-18, 22, 23, 25, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### **SPECIFICATION**

10. The disclosure is objected to because of the following informalities: A statement reading "This is a 371 of PCT/CA99/00700 FILED 8/3/99." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

#### **COMMENTS/NOTES**

11. It should be noted that no prior art has been cited against the instant invention. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious a composition and uses thereof wherein the composition comprises a metal support surface and a conjugate


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(the conjugate is releasably bound to the support surface and comprises a ligand and a targeting molecule).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
D. L. Jones  
Primary Examiner  
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November 12, 2003